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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/706,426

11/12/2003

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23872 7590 04/19/2007
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EXAMINER

RABAGO, ROBERTO

ART UNIT

PAPER NUMBER

1713

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

04/19/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/706,426

Applicant(s)

TADA ET AL.

Examiner

Roberto Rábago

Art Unit

1713

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26,28-32,34-39,41-45 and 47-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26,28-32,34-39,41-45 and 47-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/19/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/7/2007 has been entered.

Claim Rejections - 35 USC § 112

2. Claims 26, 28-32, 34-39, 41-45 and 47-51 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) In claims 26, 28-32, 34-39, 41-45 and 47-51, the requirement that the purity of the colorant composition be not less than "90% as determined by high performance liquid chromatography" is indefinite. Composition percentages are typically stated on a mass or mole basis, but in this case the value appears to be determined solely on the basis of peak area percentage from an HPLC signal. However, since none of HPLC parameters have been specified in the claims, the result would be arbitrary. At a minimum, the HPLC peak area is a direct function of the quality of the separation and the type of detection system employed. If the separation of the components is

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inadequate, an apparently "pure" peak could in fact be a combination of several impurity components. Furthermore, the various components will have different response factors in different detector systems. For example, the examples from the specification have used UV detection at 313 nm. However, the results would be necessarily different if the detector had used a different wavelength, or if a detector based upon another process (such as refractive index or fluorescence) had been used. Therefore, the requirement that HPLC is used is not, by itself, adequate to determine the scope of the purity requirement. The specification contains support for the following clause, which would resolve this issue if incorporated into the independent claims: the purity of said monoazo metal complex compound containing colorant composition being not less than 90% as determined by separation of the colorant composition by high performance liquid chromatography, wherein the purity corresponds to the peak area percent of the monoazo metal complex peak using detection at 313 nm.

(b) In claim 45 (and all claims dependent thereon) the intended scope of "high safety to the human body and low incidence of skin sensitization" cannot be determined. The claims have reasonably established a basis for determining the safety and skin sensitization for the colorant composition (i.e., by skin sensitization potential tests based on the maximization method), but the intended scope of safety and sensitization for the molded resin product cannot be determined.

(c) Claims 32 and 34-38 are indefinite because the claims are internally inconsistent, in that the resin composition is both unlimited with respect to additional components which may be included in the composition, but limited in the requirement

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that the monoazo compound must be of a purity "not less than 90%". The simultaneous requirement that the overall resin composition: (i) may include additional components of unlimited type and quantity, and (ii) is limited in the quantity of certain unidentified components, renders unclear the scope of what may and may not be included in the claimed resin composition. This issue is essentially the same as that set forth in item 4(b) of the first Office action, mailed 6/28/2006.

Remarks on Claim Interpretation

3. The following is noted with respect to the use of skin sensitization potential tests based on the maximization method, as required in all of the claims. The claims are interpreted to require the protocol described at page 9, lines 3-15, for this test. If applicants disagree with this interpretation, they should provide an alternative definition, and identify basis for such alternative definition in the specification as originally filed.

4. The following is noted with respect to the transitional phrase "consisting essentially of" as recited in claims 26 and 45. The phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention (MPEP 2111.03). In this application, it appears that two of the basic and novel characteristics are directed to: (a) the substantially exclusion (i.e., less than 10%) of impurity substances from the colorant composition, and (b) low incidence of skin sensitization for the colorant composition and the resulting resin composition. Therefore, "consisting

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essentially of" is understood to exclude components from the overall composition which: (a) increase the content of compounds corresponding to those limited to less than 10% of the colorant composition, and (b) increase the degree of skin sensitization. If applicants disagree with this interpretation, they should provide an alternative interpretation and identify basis for such alternative interpretation in the specification as originally filed.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 26, 28, 29, 32, 34, 35, 39, 41, 42, 45, 47 and 48 are rejected under 35 U.S.C. 102(e) as being anticipated by Koshida et al. (US 7,053,140).

The reference discloses in Example A and B a molding composition comprising Nylon 6, anthraquinone dye and a monoazo dye, followed by injection molding. The reference has not described either the dye purification method or the skin sensitization of the dye. However, the reference states that the monoazo dye compound was used, not a crude reaction product thereof, and therefore it is reasonable to conclude that the

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reference is using and recommending a reasonably pure dye compound, at least to the required level of 90% pure as stated in the claims. Accordingly, said reasonably pure monoazo dye compound would not be expected to exhibit the prohibited skin sensitization levels stated in the claims. The burden of proof is shifted to applicants to show that the reference example would not contain the claimed purity or skin sensitization.

Regarding the presence of the anthraquinone dye in the reference examples, and the presence of the transitional phrase "consisting essentially of" as recited in claims 26 and 45, the reference examples would still be within the scope of the claims because anthraquinone dyes are recommended as a useful adjuvant in applicants' specification at page 17, line 19, and would therefore not be expected to cause the prohibited skin sensitization, and would also not materially affect the basic and novel characteristics of the claimed invention.

Regarding the process steps of claims 32 and 39 which recite a purification step, official notice is taken that the monoazo dye complex of the reference would necessarily have undergone a purification step at some point in its history, simply as a matter of normal synthetic practice.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 30, 31, 36, 37, 43, 44, 49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Koshida et al. (US 7,053,140).

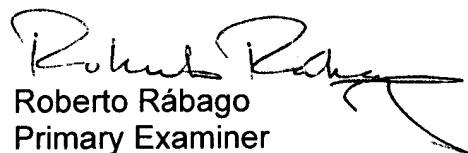
The parent claims are discussed with respect to this reference above. One of ordinary skill in the art would be motivated to include fibrous materials or inorganic fillers because they are recommended at col. 14, lines 58-63.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roberto Rábago whose telephone number is (571) 272-1109. The examiner can normally be reached on Monday - Friday from 8:00 - 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Wu can be reached on (571) 272-1114. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Roberto Rábago
Primary Examiner
Art Unit 1713

RR
April 16, 2007